

Calendar No. 530

109TH CONGRESS
2^D SESSION

S. 757

[Report No. 109–290]

To amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2005

Mr. CHAFEE (for himself, Mr. REID, Mr. TALENT, Mrs. CLINTON, Mr. HATCH, Ms. CANTWELL, Mr. ALLEN, Ms. COLLINS, Mr. GRASSLEY, Mr. CORZINE, Mr. HARKIN, Mrs. MURRAY, Mr. BINGAMAN, Mr. KENNEDY, Mr. COCHRAN, Mr. DEWINE, Mr. WARNER, Mr. COLEMAN, Mr. LAUTENBERG, Mr. DAYTON, Mr. BIDEN, Mr. VOINOVICH, Mr. JOHNSON, Mr. MCCAIN, Mrs. FEINSTEIN, Mr. SMITH, Ms. MIKULSKI, Mr. REED, Mr. FEINGOLD, Mr. SARBANES, Mr. LIEBERMAN, Mr. KOHL, Mr. SCHUMER, Mr. SUNUNU, Mrs. HUTCHISON, Ms. MURKOWSKI, Ms. STABENOW, Mr. CARPER, Mr. SPECTER, Mr. KERRY, Mr. JEFFORDS, Ms. LANDRIEU, Mr. DODD, Mrs. LINCOLN, Mrs. BOXER, Mr. BAYH, Mr. DORGAN, Mr. PRYOR, Mr. HAGEL, Mr. BENNETT, Mr. CONRAD, Ms. SNOWE, Mr. LEAHY, Mr. VITTER, Mr. SALAZAR, Mr. WYDEN, Mr. LUGAR, Mr. GRAHAM, Mr. DOMENICI, Mr. CORNYN, Mr. BAUCUS, Mrs. DOLE, Mr. MENENDEZ, Mr. SANTORUM, Mr. BURNS, Mr. KYL, and Mr. NELSON of Florida) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 24, 2006

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Breast Cancer and
 5 ~~Environmental Research Act of 2005~~”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) ~~Breast cancer is the second leading cause of~~
 9 ~~cancer deaths among American women.~~

10 (2) ~~More women in the United States are living~~
 11 ~~with breast cancer than any other cancer (excluding~~
 12 ~~skin cancer). Approximately 3,000,000 women in the~~
 13 ~~United States are living with breast cancer, about~~
 14 ~~2,000,000 of which have been diagnosed and an esti-~~
 15 ~~mated 1,000,000 who do not yet know that they~~
 16 ~~have the disease.~~

1 (3) Breast cancer is the most commonly diag-
 2 nosed cancer among women in the United States
 3 and worldwide (excluding skin cancer). In 2005, it
 4 is estimated that 269,730 new cases of breast cancer
 5 will be diagnosed among women in the United
 6 States, 211,240 invasive breast cancers and 58,490
 7 cases of ductal carcinoma in situ (DCIS).

8 (4) Approximately 40,410 women in the United
 9 States will die from the disease in 2005. Breast can-
 10 cer is the leading cause of cancer death for women
 11 in the United States between the ages of 20 and 59,
 12 and the leading cause of cancer death for women
 13 worldwide.

14 (5) A woman who lives into her 80s in the
 15 United States has a 1 in 7 chance of developing
 16 invasive breast cancer in her lifetime. This risk was
 17 1 in 11 in 1975. In 2005, a new case of breast can-
 18 cer will be diagnosed every 2 minutes and a woman
 19 will die from breast cancer every 13 minutes.

20 (6) All women are at risk for breast cancer.
 21 About 90 percent of women who develop breast can-
 22 cer do not have a family history of the disease.

23 (7) The National Action Plan on Breast Can-
 24 cer, a public private partnership, has recognized the
 25 importance of expanding the scope and breadth of

1 biomedical, epidemiological, and behavioral research
2 activities related to the etiology of breast cancer and
3 the role of the environment.

4 (8) To date, there has been only a limited re-
5 search investment to expand the scope or coordinate
6 efforts across disciplines or work with the commu-
7 nity to study the role of the environment in the de-
8 velopment of breast cancer.

9 (9) In 2003, the National Institute of Environ-
10 mental Health Sciences awarded grants to four re-
11 search centers to begin to study the prenatal-to-
12 adult environmental exposures that may predispose
13 a woman to breast cancer. The currently funded re-
14 search is examining the mammary tissue in animals
15 and young girls and study the subjects' life expo-
16 sures to environmental, nutritional, and social fac-
17 tors that impact menarche. Early menarche, begin-
18 ning menstruation before the age of 12, has been
19 shown to increase breast cancer risk later in life.

20 (10) The National Cancer Institute and the Na-
21 tional Institute of Environmental Health Sciences
22 have paired together to make those four centers pos-
23 sible. The two institutes work well together, com-
24 bining their respective areas of expertise to the best
25 advantage of the research.

1 (11) In order to take full advantage of the tre-
 2 mendous potential for avenues of prevention, the
 3 Federal investment in the role of the environment
 4 and the development of breast cancer should be ex-
 5 panded. The research conducted at the four centers,
 6 while critically important, is one small facet of the
 7 many issues that must be addressed in order to
 8 gauge the link between environmental factors and
 9 breast cancer.

10 (12) In order to understand the effect of chemi-
 11 cals and radiation on the development of cancer,
 12 multi-generational, prospective studies are probably
 13 required.

14 **SEC. 3. NATIONAL INSTITUTE OF ENVIRONMENTAL**
 15 **HEALTH SCIENCES; AWARDS FOR DEVELOP-**
 16 **MENT AND OPERATION OF RESEARCH CEN-**
 17 **TERS REGARDING ENVIRONMENTAL FAC-**
 18 **TORS RELATED TO BREAST CANCER.**

19 Subpart 12 of part C of title IV of the Public Health
 20 Service Act (42 U.S.C. 285 *l* et seq.) is amended by adding
 21 at the end the following section:

1 **~~“SEC. 463C. RESEARCH CENTERS REGARDING ENVIRON-~~**
 2 **~~MENTAL FACTORS RELATED TO BREAST CAN-~~**
 3 **~~CER.~~**

4 ~~“(a) IN GENERAL.—The Director of the Institute,~~
 5 ~~based on recommendations from the Breast Cancer and~~
 6 ~~Environmental Research Panel established under sub-~~
 7 ~~section (b) (referred to in this section as the ‘Panel’) shall~~
 8 ~~make grants, after a process of peer review and pro-~~
 9 ~~grammatic review, to public or nonprofit private entities~~
 10 ~~for the development and operation of not more than 8 cen-~~
 11 ~~ters for the purpose of conducting multidisciplinary and~~
 12 ~~multi-institutional research on environmental factors that~~
 13 ~~may be related to the etiology of breast cancer. Each such~~
 14 ~~center shall be known as a Breast Cancer and Environ-~~
 15 ~~mental Research Center of Excellence.~~

16 ~~“(b) BREAST CANCER AND ENVIRONMENTAL RE-~~
 17 ~~SEARCH PANEL.—~~

18 ~~“(1) ESTABLISHMENT.—The Secretary shall es-~~
 19 ~~tablish in the Institute of Environmental Health~~
 20 ~~Sciences a Breast Cancer and Environmental Re-~~
 21 ~~search Panel.~~

22 ~~“(2) COMPOSITION.—The Panel shall be com-~~
 23 ~~posed of—~~

24 ~~“(A) 9 members to be appointed by the~~
 25 ~~Secretary, of which—~~

1 “(i) six members shall be appointed
2 from among physicians, and other health
3 professionals, who—

4 “(I) are not officers or employees
5 of the United States;

6 “(II) represent multiple dis-
7 ciplines, including clinical, basic, and
8 public health sciences;

9 “(III) represent different geo-
10 graphical regions of the United
11 States;

12 “(IV) are from practice settings
13 or academia or other research set-
14 tings; and

15 “(V) are experienced in bio-
16 medical review; and

17 “(ii) three members shall be appointed
18 from the general public who are represent-
19 atives of individuals who have had breast
20 cancer and who represent a constituency;
21 and

22 “(B) such nonvoting, ex officio members as
23 the Secretary determines to be appropriate.

1 ~~“(3) CHAIRPERSON.—~~The members of the
 2 Panel appointed under paragraph (2)(A) shall select
 3 a chairperson from among such members.

4 ~~“(4) MEETINGS.—~~The Panel shall meet at the
 5 call of the chairperson or upon the request of the
 6 Director, but in no case less often than once each
 7 year.

8 ~~“(5) DUTIES.—~~The Panel shall—

9 ~~“(A) oversee the peer review process for~~
 10 the awarding of grants under subsection (a)
 11 and conduct the programmatic review under
 12 such subsection;

13 ~~“(B) make recommendations with respect~~
 14 to the funding criteria and mechanisms under
 15 which amounts will be allocated under this sec-
 16 tion; and

17 ~~“(C) make final programmatic rec-~~
 18 ommendations with respect to grants under this
 19 section.

20 ~~“(e) COLLABORATION WITH COMMUNITY.—~~Each
 21 center under subsection (a) shall establish and maintain
 22 ongoing collaborations with community organizations in
 23 the geographic area served by the center, including those
 24 that represent women with breast cancer.

1 “(d) COORDINATION OF CENTERS; REPORTS.—The
 2 Director of the Institute shall, as appropriate, provide for
 3 the coordination of information among centers under sub-
 4 section (a) and ensure regular communication between
 5 such centers, and may require the periodic preparation of
 6 reports on the activities of the centers and the submission
 7 of the reports to the Director.

8 “(e) REQUIRED CONSORTIUM.—Each center under
 9 subsection (a) shall be formed from a consortium of co-
 10 operating institutions, meeting such requirements as may
 11 be prescribed by the Director of the Institute. Each center
 12 shall require collaboration among highly accomplished sci-
 13 entists, other health professionals and advocates of diverse
 14 backgrounds from various areas of expertise.

15 “(f) DURATION OF SUPPORT.—Support of a center
 16 under subsection (a) may be for a period not exceeding
 17 5 years. Such period may be extended for one or more
 18 additional periods not exceeding 5 years if the operations
 19 of such center have been reviewed by an appropriate tech-
 20 nical and scientific peer review group established by the
 21 Director of the Institute and if such group has rec-
 22 ommended to the Director that such period should be ex-
 23 tended.

24 “(g) GEOGRAPHIC DISTRIBUTION OF CENTERS.—
 25 The Director of the Institute shall, to the extent prac-

1 ticable, provide for an equitable geographical distribution
 2 of centers under this section.

3 “(h) INNOVATIVE APPROACHES.—Each center under
 4 subsection (a) shall use innovative approaches to study un-
 5 explored or under-explored areas of the environment and
 6 breast cancer.

7 “(i) AUTHORIZATION OF APPROPRIATIONS.—For the
 8 purpose of carrying out this section, there is authorized
 9 to be appropriated \$30,000,000 for each of the fiscal years
 10 2006 through 2011. Such authorization is in addition to
 11 any other authorization of appropriations that is available
 12 for such purpose.”.

13 **SECTION 1. SHORT TITLE.**

14 *This Act may be cited as the “Breast Cancer and En-*
 15 *vironmental Research Act of 2006”.*

16 **SEC. 2. NATIONAL INSTITUTES OF HEALTH; AWARDS FOR**
 17 **DEVELOPMENT AND OPERATION OF RE-**
 18 **SEARCH CENTERS REGARDING ENVIRON-**
 19 **MENTAL FACTORS RELATED TO BREAST CAN-**
 20 **CER.**

21 *Part A of title IV of the Public Health Service Act*
 22 *(42 U.S.C. 281 et seq.) is amended by adding at the end*
 23 *the following:*

1 **“SEC. 404H. RESEARCH CENTERS REGARDING ENVIRON-**
 2 **MENTAL FACTORS RELATED TO BREAST CAN-**
 3 **CER.**

4 “(a) *IN GENERAL.*—The Secretary, acting through the
 5 Director of NIH, based on recommendations from the Breast
 6 Cancer and Environmental Research Panel established
 7 under subsection (b) (referred to in this section as the
 8 ‘Panel’), shall make grants to public or nonprofit private
 9 entities for the development and operation of collaborative,
 10 multi-institutional centers for the purpose of conducting
 11 multidisciplinary and multi-institutional research on envi-
 12 ronmental factors that may be related to the etiology of
 13 breast cancer. Each such center shall be known as a Breast
 14 Cancer and Environmental Research Center of Excellence.

15 “(b) *BREAST CANCER AND ENVIRONMENTAL RE-*
 16 *SEARCH PANEL.*—

17 “(1) *ESTABLISHMENT.*—The Secretary shall es-
 18 tablish within the National Institutes of Health a
 19 Breast Cancer and Environmental Research Panel.

20 “(2) *COMPOSITION.*—The Panel shall be com-
 21 posed of—

22 “(A) 9 members to be appointed by the Sec-
 23 retary, of which—

24 “(i) six members shall be appointed
 25 from among physicians and other health
 26 professionals, who—

1 “(I) are not officers or employees
2 of the United States;

3 “(II) represent multiple dis-
4 ciplines, including clinical, basic, and
5 public health sciences;

6 “(III) represent different geo-
7 graphical regions of the United States;

8 “(IV) are from practice settings,
9 academia, or other research settings;
10 and

11 “(V) are experienced in peer re-
12 view; and

13 “(ii) three members shall be appointed
14 from the general public who are representa-
15 tives of individuals who have had breast
16 cancer and who represent a constituency;
17 and

18 “(B) such nonvoting, *ex officio* members as
19 the Secretary determines to be appropriate.

20 “(3) CHAIRPERSON.—The members of the Panel
21 appointed under paragraph (2)(A) shall select a
22 chairperson from among such members.

23 “(4) MEETINGS.—The Panel shall meet at the
24 call of the chairperson or upon the request of the Di-

1 *rector of NIH, but in no case less often than once each*
2 *year.*

3 “(5) *DUTIES.—The Panel shall—*

4 “(A) *develop a comprehensive strategy con-*
5 *cerning collaborative centers that would—*

6 “(i) *result in innovative approaches to*
7 *study unexplored or underexplored areas of*
8 *the environment and breast cancer;*

9 “(ii) *outline key research questions,*
10 *methodologies, and knowledge gaps con-*
11 *cerning environmental factors that may be*
12 *related to the etiology of breast cancer;*

13 “(iii) *outline key issues concerning en-*
14 *vironmental factors that may be related to*
15 *the etiology of breast cancer; and*

16 “(iv) *result in an overall strategy to*
17 *address environmental factors related to*
18 *breast cancer;*

19 “(B) *make recommendations to the Sec-*
20 *retary with respect to the mechanisms, peer re-*
21 *view criteria, and allocations under this section;*

22 “(C) *assist in the overall program evalua-*
23 *tion; and*

24 “(D) *make recommendations for the dis-*
25 *semination of information on program process.*

1 “(c) *COLLABORATION WITH COMMUNITY.*—Each cen-
 2 ter under subsection (a) shall include community organiza-
 3 tions in the geographic area served by the center, including
 4 those that represent women with breast cancer, as integral
 5 collaborators involved at all levels of the decision-making
 6 and research in such center.

7 “(d) *COORDINATION OF CENTERS; REPORTS.*—The Di-
 8 rector of NIH shall, as appropriate, provide for the coordi-
 9 nation of information among centers under subsection (a)
 10 and ensure regular communication between such centers,
 11 and may require the periodic preparation of reports on the
 12 activities of the centers and the submission of the reports
 13 to the Director.

14 “(e) *REQUIRED CONSORTIUM.*—Each center under
 15 subsection (a) shall be formed from a consortium of cooper-
 16 ating institutions and community groups, meeting such re-
 17 quirements as may be prescribed by the Director of NIH.
 18 Each center shall require collaboration among highly ac-
 19 complished scientists, other health professionals and advo-
 20 cates of diverse backgrounds from various areas of expertise.

21 “(f) *DURATION OF SUPPORT.*—Support of a center
 22 under subsection (a) may be for a period not exceeding 5
 23 years. Such period may be extended for one or more addi-
 24 tional periods not exceeding 5 years if the operations of such
 25 center have been reviewed by an appropriate technical and

1 *scientific peer review group established by the Director of*
2 *NIH and if such group has recommended to the Director*
3 *that such period be extended.*

4 “(g) *GEOGRAPHIC DISTRIBUTION OF CENTERS.—The*
5 *Director of NIH shall, to the extent practicable, provide for*
6 *an equitable geographical distribution of centers under this*
7 *section.*

8 “(h) *AUTHORIZATION OF APPROPRIATIONS.—For the*
9 *purpose of carrying out this section, there is authorized to*
10 *be appropriated \$30,000,000 for each of the fiscal years*
11 *2007 through 2012. Such authorization is in addition to*
12 *any other authorization of appropriations that is available*
13 *for such purpose.”.*

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A BILL

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JULY 24, 2006

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